Interview Summary

Application No.	Applicant(s)
09/449,631	Renner et al
Examiner	**Group Art Unit**
Mary Mosher	1648

All participants (applicant, applicant's representative, PTO personnel):

(1) *Mary Mosher* (3) _____

(2) *Brian Del Buono* (4) _____

Date of Interview *2/15/02, 2/25/02*

Type: a)☒ Telephonic b)☐ Video Conference
c)☐ Personal [copy is given to 1)☐ applicant 2)☐ applicant's representative]

Exhibit shown or demonstration conducted: d)☒ Yes e)☐ No. If yes, brief description:
fax of proposal by MM

Claim(s) discussed: *all pending*

Identification of prior art discussed:
none

Agreement with respect to the claims f)☐ was reached. g)☒ was not reached. h)☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments:
MM proposed examiners' amendment on 2/15. MM withdrew proposal on 2/25, after realinzing that the proposed claims read on belatedly discovered prior art.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

i)☒ It is not necessary for applicant to provide a separate record of the substance of the interview (if box is checked).

Unless the paragraph above has been checked, THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

FACSIMILE COVER SHEET
PTO GROUP 1600
unofficial Fax Number (703) 305-7401

FROM: Mary Mosher

ART UNIT: 1648 (formerly 1641, 1815, 1813, or 1643)

SERIAL NO: 09/449,631

TO: Brian Del Buono

COMPANY: Stern Kessler

FAX NUMBER: 202-371-2540

OF PAGES: 6

(including this page)

IF YOU DO NOT RECEIVE A LEGIBLE COPY OR IF YOU DO NOT RECEIVE ALL OF THE PAGES, PLEASE CALL THE EXAMINER AT (703) 308-2926, OR THE GROUP RECEPTIONIST AT (703) 308-0196.

THANK YOU.

Draft

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with FILL IN on FILL IN.

The application has been amended as follows:

Claims 50-58 have been replaced by the following new claims to better describe the invention.

59. A particulate material comprising:

(1) a molecular scaffold comprising

(a) a virus-like particle; and

(b) a first attachment site,

wherein the first attachment site (I) is not naturally associated with the virus-like particle, (ii) is connected to the virus-like particle by at least one covalent bond, and (iii) is bound to the virus-like particle in an ordered and repetitive manner; and

(2) an antigen with at least one second attachment site,

wherein the second attachment site associates with the first attachment site by a bond other than a peptide bond, thereby forming an ordered and repetitive array of the antigen on the scaffold.

60. The particulate material of claim 59, wherein the antigen is an epitope or antigenic determinant.

61. The particulate material of claim 59, wherein the second attachment site is naturally associated with the antigen.

62. The particulate material of claim 59, wherein the second attachment site is not naturally associated with the antigen.

63. The particulate material of claim 59, wherein the virus-like particle is a hepatitis B particle.

64. The particulate material of claim 59, wherein the first attachment site and the second attachment site each comprise an interacting leucine zipper polypeptide.

65. The particulate material of claim 64, wherein said first attachment site is the JUN polypeptide and the second attachment site is the FOS polypeptide.

66. The particulate material of claim 59, wherein the virus-like particle is formed from one or more recombinant viral proteins from a virus selected from the group consisting of Rotavirus, Norwalk virus, Alphavirus, Foot and Mouth Disease virus, Retrovirus, Hepatitis B virus, Tobacco

Mosaic virus, Flock House virus, and Human Papillomavirus.

67. The particulate material of claim 66, wherein the first attachment site and the second attachment site each comprise an interacting leucine zipper polypeptide.

68. The particulate material of claim 67, wherein the antigen is capable of inducing an immune response against cancer cells, allergens, or agents of infectious disease.

69. The particulate material of claim 68, wherein the agents of infectious disease are selected from the group consisting of viruses, bacteria, and parasites.

70. An immunogenic composition comprising an immunogenic amount of the particulate material of claim 59 and a pharmaceutically suitable carrier.

The following is an examiner's statement of reasons for allowance:

The claim language was changed for several reasons.

The base claim is drawn to a particulate material rather than a composition. Since the invention requires all of the elements to be covalently (or noncovalently) bonded to a particle, this seemed to be better described as a particulate material, rather than a composition (which can imply a loose mixture). Furthermore, the base claim is modified to clearly exclude artificially

produced "scaffolds"containing attachment elements which are endogenous to the virus like particle. With this exclusion, the claim does not read upon prior art such as Greenstone et al (PNAS 95:1800-1805, 2/1998), Lowy et al (5,618,536), and Young et al (5,916,563).

The term "core particle" is avoided because "core" has particular limited meaning in some contexts in virology (e.g., core antigen particles versus surface antigen particles for hepatitis B virus; core particles versus virus-like particles in Bluetongue virus). The invention is better described by avoiding confusion as to whether the invention involves broadly any virus-like particles or only core-particles.

The term "organizer" is avoided as un-necessary in describing this invention. The specification states that the organizer "provides a nucleation site for creating an ordered and repetitive antigen array". However, it is apparent from the rest of the specification what is involved is actually a point of attachment to connect an antigen to the underlying ordered and repetitive structure of the virus-like particle. Since the "organizer" is not responsible for creating the order or the repetition in a virus-like particle, the term is omitted from these claims to avoid confusion.

Claim 70 is drawn to an immunogenic composition, since one skilled in the art would not question the ability of the particulate materials to induce a useful immune response against a wide range of antigens without undue experimentation, although one might question the ability to induce a response protective against the full scope of disease conditions discussed in the specification.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is (703) 308-2926. The examiner can normally be reached on Monday -Thursday and alternate Fridays from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is now (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

February 15, 2002